247d(a)(2)). However, the recommendations and processes described in the guidance are expected to assist the Agency more broadly in its continued efforts to assist sponsors in the clinical development of drugs for the treatment of COVID–19 beyond the termination of the COVID–19 public health emergency and reflect the Agency's current thinking on this issue. Therefore, within 60 days following the termination of the public health emergency, FDA intends to revise and replace this guidance with any appropriate changes based on comments received on this guidance and the Agency's experience with implementation.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''COVID–19: Developing Drugs and Biological Products for Treatment or Prevention.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). Under the PRA, Federal Agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR parts 312 and 320 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 58 regarding good laboratory practice for nonclinical laboratory studies have been approved under OMB control number 0910–0119; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 320 have been approved under OMB control number 0910–0291; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in FDA's draft guidance for industry entitled ''Formal Meetings Between FDA and Sponsors and Applicants of Prescription Drug User Fee Act Products'' have been approved under OMB control number 0910–0429; the collections of information in FDA's final guidance for clinical trial sponsors entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under OMB control number 0910–0581; and the collections of information in FDA's final guidance for industry entitled ''Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring'' have been approved under OMB control number 0910–0733.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders, or https://www.regulations.gov.*

Dated: May 13, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10635 Filed 5–18–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold a virtual meeting. The meeting will be open to the public and public comment will be heard during the meeting.

DATES: The meeting will be held on Tuesday, June 9, 2020. If needed, additional sessions and may be added on Wednesday, June 10, 2020. The confirmed meeting times and agenda will be posted on the NVAC website at *http://www.hhs.gov/nvpo/nvac/meetings/index.html* as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted online at: *http://www.hhs.gov/nvpo/nvac/meetings/index.html* at least one week prior to the meeting. Pre-registration is required for those who wish to attend the meeting or participate in public comment. Please register at *http://www.hhs.gov/nvpo/nvac/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Ann Aikin, Acting Designated Federal Officer, at the Office of Infectious Disease and HIV/AIDS Policy, U.S. Department of Health and Human Services, Mary E. Switzer Building, Room L618, 330 C Street SW, Washington, DC 20024. Email: *nvac@hhs.gov.* Telephone: 202–795–7611.

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of HHS was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

During the June 2020 NVAC meeting, sessions will focus on coronavirus vaccine development, reimbursement and changes in billing and coverage with updates from members. Please note that agenda items are subject to change, as priorities dictate. Information on the final meeting agenda will be posted prior to the meeting on the NVAC website: *http://www.hhs.gov/nvpo/nvac/index.html.*

Members of the public will have the opportunity to provide comment at the NVAC meeting during the public comment period designated on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Individuals are also welcome to submit written comments. Written comments should not exceed three pages in length. Individuals submitting written comments should email their comments

to *nvac@hhs.gov* at least five business days prior to the meeting.

Dated: May 13, 2020.

Ann Aikin,

Acting Designated Federal Official, Office of the Assistant Secretary for Health.

[FR Doc. 2020–10656 Filed 5–18–20; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will be holding the 67th full Council meeting utilizing virtual technology. The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is required for both public participation and comment.

Individuals who wish to participate in the meeting and/or provide public comment should pre-register by sending an email to *PACHA@hhs.gov.* Individuals will be required to provide their name, organization, and email address to pre-register. Agenda items will include discussing the 2019 novel coronavirus (COVID–19) and the impact on people living with, or at risk of, HIV and implementing the *Ending the HIV Epidemic* initiative post COVID–19. The meeting agenda will be posted on the PACHA website at *https://www.hiv.gov/federal-response/pacha/about-pacha* as soon as it becomes available.

DATES: The meeting will be held on Monday, June 1, 2020, from approximately 2:00 p.m. to 5:00 p.m. (ET) and on Tuesday, June 2, 2020 from approximately 2:00 p.m. to 5:00 p.m. (ET). This meeting will be conducted utilizing virtual technology.

ADDRESSES: Instructions regarding attending this meeting virtually will be posted one week prior to the meeting at: *https://www.hiv.gov/federal-response/pacha/about-pacha.*

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, MPA, Public Health Analyst, Presidential Advisory Council on HIV/AIDS, 330 C Street SW, Room L609A, Washington, DC 20024; (202) 795–7622 or *PACHA@hhs.gov.* Additional information can be obtained by accessing the Council's page on the HIV.gov site at *www.hiv.gov/pacha.*

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996 and is currently operating under the authority given in Executive Order 13889, dated September 27, 2019. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective prevention and care of HIV infection and AIDS. The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House.

Dated: May 13, 2020.

B. Kaye Hayes,

Principal Deputy Director, Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health.

[FR Doc. 2020–10639 Filed 5–18–20; 8:45 am]

BILLING CODE 4150–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Acute Neural Injury and Epilepsy Study Section.

Date: June 18–19, 2020.

Time: 8:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Dr., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Paula Elyse Schauwecker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5201, Bethesda, MD 20892, 301–760–8207, *schauweckerpe@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Nursing and Related Clinical Sciences Study Section.

Date: June 22–23, 2020.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Dr., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Preethy Nayar, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3156, Bethesda, MD 20892, 301–402–4469, *nayarp2@csr.nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Drug Discovery and Molecular Pharmacology Study Section.

Date: June 22–23, 2020.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Dr., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jeffrey Smiley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301–594–7945, *smileyja@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Cancer, Heart, and Sleep Epidemiology B Study Section.

Date: June 22–23, 2020.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Dr., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Gianina Ramona Dumitrescu, Ph.D., MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4193–C, Bethesda, MD 28092, 301–827–0696, *dumitrescurg@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurotransporters, Receptors, and Calcium Signaling Study Section.

Date: June 23, 2020.

Time: 8:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Dr., Bethesda, MD 20892 (Virtual Meeting).